WEST VIRGINIA LEGISLATURE
FIRST REGULAR SESSION, 1999

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ENROLLED

House Bill No. 2796
(By Delegates Border, Leach and Perdue (By Request))

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Passed March 11, 1999
In Effect Ninety Days from Passage
ENROLLED
H. B. 2796

(BY DELEGATES BORDER, LEACH AND PERDUE (BY REQUEST))

[Passed March 11, 1999; in effect ninety days from passage.]

AN ACT to amend and reenact sections six-a, nine and fourteen, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended; to further amend said article by adding thereto a new section, designated section nine-a; and to amend and reenact section seven, article eight, chapter sixty-a of said code, all relating to fees for licensing and permits to operate for pharmacists, pharmacies, drugstores and wholesale drug distributors payable to the West Virginia Board of Pharmacy; establishing an initial fee and a renewal fee for an application for a permit for mail-order pharmacies and drugstores; increasing the renewal fees for licensing and operation permits for pharmacists; increasing the licensing fee for wholesale drug distributors; and authorizing future fee modifications to be made by legislative rule.

Be it enacted by the Legislature of West Virginia:

That sections six-a, nine and fourteen, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted; that said article be further amended by adding thereto a new section, designated section nine-a; and that section seven, article eight, chapter sixty-a of said code be amended and reenacted, all to read as follows:
CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-6a. Permits for mail-order houses.

(a) Every mail-order house which dispenses drugs or medicines through the United States mail or otherwise from any point in the state of West Virginia to any point outside of the state of West Virginia shall be registered as a pharmacy or drugstore pursuant to the provisions of section fourteen of this article: Provided, That the provisions of this subsection do not apply to any mail-order house which operates solely as a wholesale distributor. Every initial application for a permit shall be accompanied by a fee of five hundred dollars. The fee for renewal of the permit or license shall be five hundred dollars annually.

(b) Every mail-order house which dispenses drugs or medicines through the United States mail or otherwise from any point outside of the state of West Virginia to any point within the state of West Virginia shall, as a condition precedent to being qualified and authorized to transact business in the state of West Virginia, annually register with the board of pharmacy to conduct such business in this state. Every initial application for a permit shall be accompanied by a fee of five hundred dollars. The fee for renewal of the permit or license shall be five hundred dollars annually. Every business shall be required to provide to the board of pharmacy satisfactory evidence that it qualifies as a pharmacy or drugstore and that the business is licensed or registered as a pharmacy or drugstore in the state where the business dispenses prescriptions by mail order to residents of this state. The board of pharmacy shall promulgate rules, in accordance with the provisions of article three, chapter twenty-nine-a of this code, for the procedures of registration pursuant to this subsection: Provided, That the provisions of this subsection do not apply to any mail-order house which operates solely as a wholesale distributor.

§30-5-9. Fees.
The board of pharmacy shall charge and collect the following fees, in addition to those provided in article one of this chapter and in sections five, fourteen and sixteen of this article: For renewing the licensure of a pharmacist, fifty dollars; to license an intern pharmacist, ten dollars plus five dollars for each of the remaining periods of his or her internship; to register a consultant pharmacist, twenty dollars for the initial application and ten dollars for each additional application; and to register a pharmacy technician, twenty-five dollars and ten dollars for each renewal.

§30-5-9a. Authorization for future fee modifications to be made by rule.

Notwithstanding any other provision of this code to the contrary, beginning on the first day of July, one thousand nine hundred ninety-nine, the board may set any fee authorized under this article by legislative rule, in accordance with article three, chapter twenty-nine-a of this code.

§30-5-14. Pharmacies to be registered; permit to operate; fees; pharmacist to conduct business.

(a) The board of pharmacy shall require and provide for the annual registration of every pharmacy doing business in this state. Any person, firm, corporation or partnership desiring to operate, maintain, open or establish a pharmacy in this state shall apply to the board of pharmacy for a permit to do so. The application for such permit shall be made on a form prescribed and furnished by the board of pharmacy, which, when properly executed, shall indicate the owner, manager, trustee, lessee, receiver, or other person or persons desiring such permit, as well as the location of such pharmacy, including street and number, and any other information as the board of pharmacy may require. If it is desired to operate, maintain, open or establish more than one pharmacy, separate application shall be made and separate permits or licenses shall be issued for each.

(b) Every initial application for a permit shall be accompanied by the required fee of one hundred fifty dollars. The fee for renewal of such permit or license shall be one hundred dollars annually.
(c) If an application is approved, the secretary of the board of pharmacy shall issue to the applicant a permit or license for each pharmacy for which application is made. Permits or licenses issued under this section shall not be transferable and shall expire on the thirtieth day of June of each calendar year, and if application for renewal of permit or license is not made on or before that date, or a new one granted on or before the first day of August, following, the old permit or license shall lapse and become null and void and shall require an inspection of the pharmacy and a fee of one hundred fifty dollars plus one hundred fifty dollars for the inspection.

(d) Every place of business so registered shall employ a pharmacist in charge and operate in compliance with the general provisions governing the practice of pharmacy and the operation of a pharmacy.

(e) The provisions of this section shall have no application to the sale of nonprescription drugs which are not required to be dispensed pursuant to a practitioner's prescription.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.


§60A-8-7. Wholesale drug distributor licensing requirements.

All wholesale distributors and pharmacy distributors shall be subject to the following requirements:

(a) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license to do so from the board of pharmacy and paying any reasonable fee required by the board of pharmacy, such fee not to exceed four hundred dollars per year.

(b) The board of pharmacy may grant a temporary license when a wholesale drug distributor first applies for a license to operate within this state and the temporary license shall remain valid until the board of pharmacy finds that the applicant meets or fails to meet the requirements for regular licensure, except
that no temporary license shall be valid for more than ninety
days from the date of issuance. Any temporary license issued
pursuant to this subdivision shall be renewable for a similar
period of time not to exceed ninety days pursuant to policies
and procedures to be prescribed by the board of pharmacy.

(c) No license may be issued or renewed for a wholesale
drug distributor to operate unless the distributor operates in a
manner prescribed by law and according to the rules promul-
gated by the board of pharmacy with respect thereto.

(d) The board of pharmacy may require a separate license
for each facility directly or indirectly owned or operated by the
same business entity within this state, or for a parent entity with
divisions, subsidiaries, or affiliate companies within this state
when operations are conducted at more than one location and
there exists joint ownership and control among all the entities.

(e) (1) As a condition for receiving and retaining any
wholesale drug distributor license issued pursuant to this article,
each applicant shall satisfy the board of pharmacy that it has
and will continuously maintain:

(A) Acceptable storage and handling conditions plus
facilities standards;

(B) Minimum liability and other insurance as may be
required under any applicable federal or state law;

(C) A security system which includes after hours central
alarm or comparable entry detection capability, restricted
premises access, adequate outside perimeter lighting, compre-
hensive employment applicant screening and safeguards against
employee theft;

(D) An electronic, manual or any other reasonable system
of records describing all wholesale distributor activities
governed by this article for the two-year period following
disposition of each product and being reasonably accessible as
defined by board of pharmacy regulations during any inspection
authorized by the board of pharmacy;

(E) Officers, directors, managers and other persons in
charge of wholesale drug distribution, storage and handling,
who must at all times demonstrate and maintain their capability
of conducting business according to sound financial practices
as well as state and federal law;

(F) Complete, updated information to be provided the board
of pharmacy as a condition for obtaining and retaining a license
about each wholesale distributor to be licensed under this article
including all pertinent licensee ownership and other key
personnel and facilities information determined necessary for
enforcement of this article, with any changes in the information
to be submitted at the time of license renewal or within twelve
months from the date of the change, whichever occurs first;

(G) Written policies and procedures which assure reason-
able wholesale distributor preparation for protection against and
handling of any facility security or operation problems,
including, but not limited to, those caused by natural disaster or
government emergency, inventory inaccuracies or product
shipping and receiving, outdated product or other unauthorized
product control, appropriate disposition of returned goods and
product recalls;

(H) Sufficient inspection procedures for all incoming and
outgoing product shipments; and

(I) Operations in compliance with all federal legal require-
ments applicable to wholesale drug distribution.

(2) The board of pharmacy shall consider, at a minimum,
the following factors in reviewing the qualifications of persons
who engage in wholesale distribution of prescription drugs with
this state:

(A) Any conviction of the applicant under any federal, state
or local laws relating to drug samples, wholesale or retail drug
distribution or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal,
state or local laws;

(C) The applicant’s past experience in the manufacture or
distribution of prescription drugs, including controlled sub-
stances;
(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(E) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drug, including controlled substances;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Compliance with requirements to maintain and make available to the board of pharmacy or to federal, state or local law-enforcement officials those records required by this article; and

(H) Any other factors or qualifications the board of pharmacy considers relevant to and consistent with the public health and safety, including whether the granting of the license would not be in the public interest.

(3) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration (FDA); and in case of conflict between any wholesale drug distributor licensing requirement imposed by the board of pharmacy pursuant to this subsection and any food and drug administration wholesale drug distributor licensing guideline, the latter shall control.

(f) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when the agent or employee is acting in the usual course of business or employment.

(g) The issuance of a license pursuant to this article does not change or affect tax liability imposed by this state's department of tax and revenue on any wholesale drug distributor.

(h) The board of pharmacy may adopt rules pursuant to section nine of this article which permit out-of-state wholesale
drug distributors to obtain any license required by this article on
the basis of reciprocity to the extent that: (i) An out-of-state
wholesale drug distributor possesses a valid license granted by
another state pursuant to legal standards comparable to those
which must be met by a wholesale drug distributor of this state
as prerequisites for obtaining a license under the laws of this
state; and (ii) such other state would extend reciprocal treatment
under its own laws to a wholesale drug distributor of this state.
That Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originating in the House.

Takes effect ninety days from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker of the House of Delegates

The within ____________ day of ____________, 1999, approved this the 27th day of November, 1999.

Governor